

AUG 28 2003

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**510(k) SUMMARY**

**for the Inion OTPS™ Biodegradable Pin**

**MANUFACTURER**

Inion Ltd.

Lääkärintie 2

FIN-33520 Tampere

Contact Person:

Hanna Marttila

Regulatory Affairs Manager

Lääkärintie 2

FIN-33520 Tampere

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[Hanna.Marttila@Inion.fi](mailto:Hanna.Marttila@Inion.fi)

**DEVICE NAME**

Trade name: Inion OTPS™ Biodegradable Pin

Common/Usual Name: Pin, Fixation

**ESTABLISHMENT REGISTRATION NUMBER**

9710629

**DEVICE CLASSIFICATION AND PRODUCT CODE**

Classification panel: Orthopedic

Regulatory Class: Class II

21 CFR 888.3040 – Smooth or threaded metallic bone fixation fastener, 87-HWC

**PREDICATE DEVICES**

Bionx Implants, Inc.; PLLA Pin (K010983)

DePuy ACE; OrthoSorb Absorbable Pin (K901456)

Synthes; Polypin (K961608)

Pin

Date: 20.5.2003

Status: Final

## **DEVICE DESCRIPTION AND PRINCIPLES OF OPERATION**

The Inion OTPS™ Biodegradable Pin is indicated for maintenance of alignment and fixation of bone fractures, osteotomies, arthrodeses or bone grafts in the presence of appropriate additional immobilization (e.g. rigid fixation implants, cast, brace). Pins are offered in several dimensions and lengths typical for this application.

The Inion OTPS™ Biodegradable Pin is made of resorbable polylactic acid / trimethylenecarbonate copolymers [Poly (L-lactide-co-D,L-lactide) and poly (L-lactide-co-trimethylenecarbonate)]. Pins are offered both undyed and coloured for better visualization during surgical operation. The Inion OTPS™ Biodegradable Pin gradually loses its strength during 18-36 weeks in vivo with complete strength loss and resorption within two to four years.

## **EQUIVALENCE TO MARKETED PRODUCTS**

The Inion OTPS™ Biodegradable Pin is substantially equivalent to those of the previously accepted and clinically successfully used biodegradable pins intended for similar indications.

Inion OTPS™ Biodegradable Pin, SmartPin (K010983), OrthoSorb Absorbable Pin (K901456) and Polypin (K961608) have the same principles of operation and very similar design characteristics. Mechanical testing demonstrates that the device is substantially equivalent to the predicate ones. Differences between The Inion OTPS™ Biodegradable Pin and predicate devices do not raise any new questions of safety and effectiveness.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

AUG 28 2003

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Ms. Hanna Marttila  
Regulatory Affairs Manager  
Inion Ltd.  
Lääkärinkatu 2  
FIN-33520 Tampere  
Finland

Re: K031712  
Trade/Device Name: Inion OTPS™ Biodegradable Pin  
Regulation Number: 21 CFR 888.3040  
Regulation Name: Smooth or threaded metallic bone fixation fastener  
Regulatory Class: II  
Product Code: HTY  
Dated: May 20, 2003  
Received: June 10, 2003

Dear Ms. Marttila:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

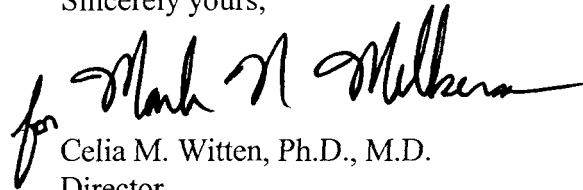
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2 - Ms. Hanna Marttila

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read "for Celia M. Witten". The signature is written in a cursive, flowing style.

Celia M. Witten, Ph.D., M.D.  
Director  
Division of General, Restorative  
and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

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*K 031712***D STATEMENT OF INDICATIONS FOR USE****Applicant: Inion Ltd.****510(k) Number:****Device Name: Inion OTPS™ Biodegradable Pin****Indications:**

The Inion OTPS™ Biodegradable Pin is indicated for maintenance of alignment and fixation of bone fractures, osteotomies, arthrodeses or bone grafts in the presence of appropriate additional immobilization (e.g. rigid fixation implants, cast, brace).

**Contraindications:**

The Inion OTPS™ Biodegradable Pin should not be used in fractures and osteotomies of diaphyseal bone or in cases with insufficient quality or quantity of bone. Other contraindications are active or potential infections, patient conditions including limited blood supply, and where patient cooperation cannot be guaranteed (e.g. alcoholism, drug abuse).

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Prescription use *3/2* Over the Counter use *N6*

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Per 21 CFR 801.109)

*for Mark A. Miller*  
(Division Sign-Off)  
Division of General, Restorative  
and Neurological Devices

Pin

510(k) Number *K031712*

Date: 20.5.2003  
Status: Final